

Remarks

Claims 1-3, 7-9, 11 & 20 were pending in this Application prior to the entry of the above-amendments. Claims 1 & 8 are currently amended. Claim 9 is canceled herein. Applicant requests reconsideration of the claims in light of the amendments above and remarks below.

The Examiner has indicated that claim 8 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Currently amended claim 8 represents consolidation of the subject matter of claims 1 and 8. Allowance of the claim is requested.

The Examiner has rejected claims 1-20 under 35 U.S.C. 112, paragraph 1, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection and, for the reasons that follow maintain that claims 1-3, 7-8, 11 & 20 are full, clear, and concise as to enable any person skilled in the art to make and use their invention.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The examiner must also consider whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

On page 7, Applicants have explained that the product has one or more characteristics selected from: i) a molecular weight of about 1,100 kDa as measured by 3% polyacrylamide gel electrophoresis; ii) capable of displaying a Fourier transform infrared spectrum similar to that shown in Figure 3, with the peaks indicated in Table 2; iii)

capable of displaying a NMR proton spectrum similar to that shown in Figure 1; iv) sensitivity to the action of chondroitinase ABC I; v) sensitivity to the action of N-glycanase; vi) resistance to the action of chondroitinases ACI and B; vii) resistance to the action of proteinase K; viii) resistance to the action of papain; ix) sensitivity to the action of neuraminidase. Thus Applicants have defined the structure by analytical techniques known to one of ordinary skill in the art. This information not only defines the structure but also delimits it from other known products.

Applicants have also described how to collect and purify the product. See e.g. example I. Applicants have also shown the molecular weight of the product (page 20), the susceptibility of the product to proteinases (page 20); NMR characterization of the product (page 21), FTIR characterization of the product (page 21); gas chromatography analysis (page 23), monosaccharide composition of *M. glacialis* product (page 24), preparation and use of the product (page 32), as well as properties of the product of the invention (see all of Example 8). Thus, the specification contains working examples and data which is sufficient information for one to make and use the claimed invention.

In view of the forgoing, Applicants submit that claims 1-3, 7-8, 11 & 20 are supported by the disclosure in the application in that the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention. Moreover, since the working examples show the preparation of the claimed product, Applicants submit that the scope of enablement provided to one of ordinary skill in the art by the disclosure is commensurate with the scope of protection sought by claims 1-3, 7-8, 11 & 20. Applicants, therefore, respectfully request that the 112, paragraph 1 rejection be withdrawn.

The Examiner has also rejected claims 1-20 under 35 U.S.C. 112, paragraph 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that the claims are incomplete in that none of the claims provide the structure or specific properties to

reasonably indicate the claimed product. The Examiner further stated that the claimed product should include melting point, density, and molecular weight, physical and chemical properties as well as the IR, UV, and NMR properties, and that the claimed properties must be essentially positive limitations and not intended limitations. Applicants respectfully traverse the rejection and for the following reasons maintain that claims 1-3, 7-8, 11 & 20 are definite and unambiguous.

First, independent claims 1 & 20 require, among other things, glycoprotein having a molecular weight of about 1,100 kDa as measured by 3% polyacrylamide gel electrophoresis. Clearly these independent claims include a positive limitation to molecular weight and reconsideration is urged.

Second, independent claims 1 & 20 require, among other things, a glycoprotein exhibiting at least one characteristic selected from the group consisting of:

- a) sensitivity to the action of chondroitinase ABC I,
- b) sensitivity to the action of N-glycanase,
- c) resistance to the action of chondroitinases ACI and B,
- d) resistance to the action of proteinase K,
- e) resistance to the action of papain, and
- f) sensitivity to the action of neuraminidase.

Each of the claimed properties do not have to be positive limitations. Negative limitations define an invention in terms of what the invention is not, rather than what it is. There is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. In re Barr, 170 USPQ 330 (CCPA 1971) (the negative functional limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear). See also In re Wakefield, 164 USPQ 636, 638, 640 (CCPA 1970) (A claim to synthetic polyisoprene which recited the limitation

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"being free from the proteins, soaps, resins and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product was considered definite because each recited limitation was definite.).

Applicants respectfully submit that the disclosure and claims are sufficient for one skilled in the art to understand, and claims 1-3, 7-8, 11 & 20 should not be rejected because of the Examiners preferences for the inclusion of limitations such as melting point, boiling point, IR, UV, and NMR properties, especially when other modes of expression selected by the Applicants satisfy the statutory requirements. See MPEP 2173.02. Moreover, Applicant submits that such physiochemical parameters may be more appropriate to a single pure chemical such as sodium chloride or aspirin, but not a glycoprotein, which like all biological macromolecules has no melting or boiling point, but decomposes at high temperatures. Applicants, therefore, respectfully request that the 112, paragraph 2 rejection be withdrawn.

It is respectfully submitted that all claims pending in the application, namely claims 1, 2, 3, 7, 8, 11 & 20, are in order for allowance and earlier notification of such condition is requested.

Respectfully submitted,



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